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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/393,168	09/10/1999	TOSHIMITSU ISHIKAWA	724-P10-2589	2333

7590 08/31/2004

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EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 08/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



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09/1393168

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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EXAMINER

ART UNIT

PAPER NUMBER

8/9/08

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 7/7/03☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-22 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.☒ Claim(s) 1-22 is/are rejected.☐ Claim(s) _____ is/are objected to.☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been☐ received.☐ received in Application No. (Series Code/Serial Number) _____☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskel et al. (US Patent No. 3,851,051) in view of Tanner et al. (US Patent No. 5,569,466).

Miskel et al., see Example 1 column 6, teach a soft capsule comprising a water-soluble dietary fiber (citrus pectin) and a material of limited-oil solubility (diphenhydramine). No dispersion stabilizer and fat and oil material or oil soluble material is present.

Further, Miskel et al., see Example 50, teach a soft capsule comprising a water-soluble dietary fiber (apple pectin), a material of limited oil-solubility (glycerin) and a fat and oil material or oil-soluble material (vitamin E).

Lastly, Miskel et al., see Example 43, teach a soft capsule comprising a water-soluble dietary fiber (citrus pectin) and a material of limited oil-solubility (sodium saccharin). No dispersion stabilizer and fat and oil material or oil-soluble material is present.

However, Miskel et al. do not teach a homogenous mixture of the medicinal liquid in the soft capsule.

Tanner et al. teach fill compositions for soft gel capsules (title) comprising an active agent dissolved or suspended in a carrier liquid (abstract). Tanner et al. teach

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homogenization of actives and solubilizing agents (column 4, lines 47-50, and 65-66).

Water is disclosed (column 3, lines 61).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a soft gel capsule comprising citrus pectin, to achieve high stability in view of Miskel et al.

As to the claimed homogenization, Tanner et al. teach that homogenization is well known in the art of making a soft gel capsule. One of ordinary skill in the art would recognize that homogenization provides a stable mixture.

Applicants argue that Miskel et al teach a rigid gel rather than a liquid suspension. However, Miskel et al disclose a suspension (column 3 lines 40-44) that remains fluid at 30-40°C during the filling of a soft gelatin capsule (column 3, line 71 – column 4 line 6). Applicant s also disclose a liquid suspension at temperatures of 40°C and 50°C (page 7 line 31, page 8 line 14, page 9, line 11, page 10, line 27). Applicants are silent regarding the form of their suspension below 30°C.

Applicants further argue that homogenization would destroy the rigid gel system. However, that such a result would incur is mere opinion. As to the claimed properties, they must be possessed by the obvious combination because it is the same as that claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is (571) 272-0633. The examiner can normally be reached on Monday to Friday 9 Am 5 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Webman/LR
August 10, 2004


EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500